Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 7. This sheet, replaces the previously provided sheet including Fig. 7. In Figure 7, the figure has been redrawn to insert the demarcation lines for the treatment period appropriately. All data remains the same, and the lines showing the metes and bounds of the treatment period, which were drawn in error, have been modified to correspond to the written description, as originally filed.

Attachment: Includes a Replacement Sheet and an Annotated Sheet Showing Changes

REMARKS/ARGUMENTS

In the specification, the paragraphs beginning at page 9, line 5; page 9, line 14; page 19, line 11; page 20, line 3; page 20, line 14; and page 21, line 6; have been amended to eliminate erroneous reference to S.N. 10/348,284.

Claims 1-5, 7-31 and 33-36 remain in this application.

Claims 6 and 32 have been canceled.

Claims 9-31 and 33-36 have been withdrawn.

In view of the examiner's earlier restriction requirement, applicant retains the right to present claims 9-31 and 33-36 in a divisional application.

In response to the Office Action of July 12, 2006, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Objections to the Specification:

The Examiner has established a priority date of June 23, 2003 for the reference to "delaying disease progression". The Examiner has further objected to the disclosure, indicating a lack of antecedent basis for the terminology regarding the method of "delaying disease progression" and the terminology "identifying characteristics".

Accordingly, the reference to "identifying characteristics" has been removed from the claims.

The reference to "delaying disease progression" can be found at page 23, line 10 of the originally filed disclosure, and further reference to utilizing body weight as a surrogate indicator of disease progression can be found, inter alia, at page 22, lines 20-23.

The amendment filed February 2, 2004, stands objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. The added material which is not supported by the original disclosure is as follows:

> "This application is a continuation-in-part of application S.N. 10/348,231, filed January 21, 2003, the contents of which are herein incorporated by reference."

The Examiner points out that a review of the filing papers reveals that the newly claimed priority document is mentioned in none of the Declarations as originally filed or the originally filed transmittal papers. Thus, the amendment to the specification to revise the claimed priority is new matter. Applicant has been required to cancel the new matter in the response to this Office action.

In review of this issue, Applicants have noted that the cross-reference to related applications was indeed in error as originally filed, and further that the Examiner is correct in indicating that the amendment, as noted *supra*, does introduce new matter. A "Petition to Accept Unintentionally Delayed Domestic Priority Claim under 37 Cfr 1.78(a)" along with an amendment to remove the language regarding incorporation by reference has been filed on even date herewith, a copy of which is attached for the Examiner's convenience. Applicants believe that upon granting of the petition and entry of the amendment, the objection to the specification will have been obviated.

Objections to the Drawings:

The drawings stand objected to because the amended Figure 7, received January 23, 2004, is alleged to add new matter.

The Examiner points out that Applicants argue on p. 3, 2nd para., in remarks made with the amendment received January 23, 2004, that the treatment period began 21 days post-implantation of PC-3 prostate cancer cells. The Examiner further points out that the Applicants argue that the administration was discontinued at 43 days post-implantation and that the treatment period, as demarcated by the dashed lines, in the amended Figure

7, appears to be from about 17 days post-implantation to 35 days post-implantation. Although argued by Applicants, the Examiner indicates that Applicants do not point to support in the specification for the amendment and review of the specification did not reveal support for the amendment.

Applicant has therefore been required to cancel the new matter in the response to this Office action.

Accordingly, Figure 7 has now been clarified. The lines of demarcation of the treatment period had been inadvertently misplaced. This has now been corrected so as to correspond with the written description, as originally filed, at page 24. No new matter is incorporated via this amendment.

Rejections under 35 USC 112:

Claims 1-8 stand rejected under 35 USC 112, second paragraph because claim 1 recites the phrase "identifying characteristics". The claims are deemed to be indefinite because the specification provides no definition of "identifying characteristics". Thus it is not possible to determine if the identifying characteristics of the claimed product used in the claimed method are drawn to the product's characteristics as a monoclonal antibody, as a protein, as a binder to a particular antigen, or as a binder to a

cancer cell. Given the above, the metes and bounds of the subject matter claimed cannot be determined and neither the specification nor the claims as originally filed particularly points out or distinctly claims the subject matter which applicant regards as the invention.

Accordingly, the claims have been amended to remove the phrase "identifying characteristics" and have been amended to recite "the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-4890".

This language is believed to succinctly and specifically claim the specific isolated monoclonal antibody produced from the hybridoma deposited with the ATCC as accession number PTA-4890. Basis for this amendment may be found in the specification at page 7, lines 2-8 and at page 18, line 20 - page 19, line 8.

Claim 5 was rejected since the claim from which it depended was inadvertently left out. Claim 5 has now been amended to depend from claim 1. Basis for this may be found in claim 5 of the original disclosure.

Claim 8 stands rejected as being indefinite because it recites the phrase a "chimerized antibody". The Examiner indicates that the exact meaning of the word -chimera- is not known; the term chimera is generic to a class of antibodies which

are products of genetic shuffling of antibody domains and other active proteins; the term encompasses antibodies fused to non-immunoglobulin proteins as well as antibodies wherein any domain of the antibody is substituted by corresponding regions or residues of human antibodies including but not limited to CDR grafted antibodies, and that the metes and bounds of the claim protection sought cannot be determined.

Claim 8 has been amended to recite:

"The method of claim 1 wherein said antibody is a chimeric antibody produced from the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-4890."

Basis for this amendment may be found at page 7, lines 2-7 of the specification as originally filed. The metes and bounds of the claim now specifically relate to chimeric antibodies produced from the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-4890.

Claims 1-8 further stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a

monoclonal antibody or antigen binding fragment thereof which is encoded by a clone deposited with the ATCC as accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended does not reasonably provide enablement for a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the **identifying characteristics** of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and -survival is extended.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Accordingly, the claims have been amended to remove the phrase "identifying characteristics" and have been amended to recite "the isolated monoclonal antibody produced by the

hybridoma deposited with the ATCC as accession number PTA-4890".

Claims 1-6 and 8 are further rejected under 35 USC § 112 as being drawn to the treatment of a human tumor in a human using a mouse antibody. The Examiner indicates that such treatment could not be predicted to be successful, e.g. due to development of a HMA response.

Applicant respectfully disagrees with the Examiner's conclusions. Numerous references exist in the literature regarding the utility of the murine antibody mAb 4D5 for the treatment of human tumors, notably human breast cancers. Therefore, based on demonstrable success with mouse monoclonals against human tumors, it is reasonable to predict that non-humanized antibodies will be useful in the treatment of human tumors, particularly as a HAMA response is certainly not immediate, and may, in fact, not occur to an extent which will negate the demonstrated utility of the mouse antibody.

Claims 1-8 are further rejected under 35 USC § 112 as the claims are directed toward delaying disease progression broadly, but the disclosure is directed toward use of the parameter of reduction of body weight in prostate cancers, and therefore the claims are not commensurate in scope for delay of disease progression in all cancers.

The specification teaches use of body weight as a surrogate marker of disease progression in a xenograft model of prostate cancer in SCID mice, and further goes on to indicate a reduction of tumor burden in both breast and prostate tumors as a result of treatment with the instant PTA-4890 antibody. It is improper to limit the claims to a specific exemplary embodiment. The claims are drawn to treatment of a human tumor wherein the tumor expresses an antigen which specifically binds to the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-4890. Further, the rejection on the basis of alleged failure to treat metastatic disease is not understood. Firstly, all cancers do not metastasize. Secondly, the demonstration that tumor burden is reduced or reversed by treatment with the claimed antibody and that weight loss is prevented is indicative of a delay in disease progression, is evidence, in and of itself of a delay in disease progression.

It is respectfully submitted that a valid model could be easily developed for any cancer expressing such an antigen to codify reduction of body weight as a surrogate marker of disease progression, and for this and the reasons stated above, the rejection should therefore be withdrawn and the claims passed to issue.

Rejections under 35 USC 102(b)

The rejection under 35 USC 102(b) of claims 1,6 and 7 over Cobleigh is deemed moot in view of the claims having been amended to remove the phrase "identifying characteristics" and recital of the terminology "the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-4890".

Rejection under 35 USC 103(a)

Likewise, the rejection under 35 USC 103(a) over Cobleigh et al in view of in view of Dillman and Helstrom is likewise moot in view of the above-referenced amendments.

Double Patenting Rejections:

Rejections under the judiciously created doctrine of obviousness-type double patenting have been asserted over U.S. 7,009,040; S.N. 10/810,751; S.N. 10/743,451; S.N. 11/370,203; S.N. 11/367,798; S.N. 11/362,452; and S.N. 11/321.624.

Terminal Disclaimers and the requisite fees are included herewith, thereby obviating the rejections or provisional rejections.

SUMMARY

In light of the foregoing remarks and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,

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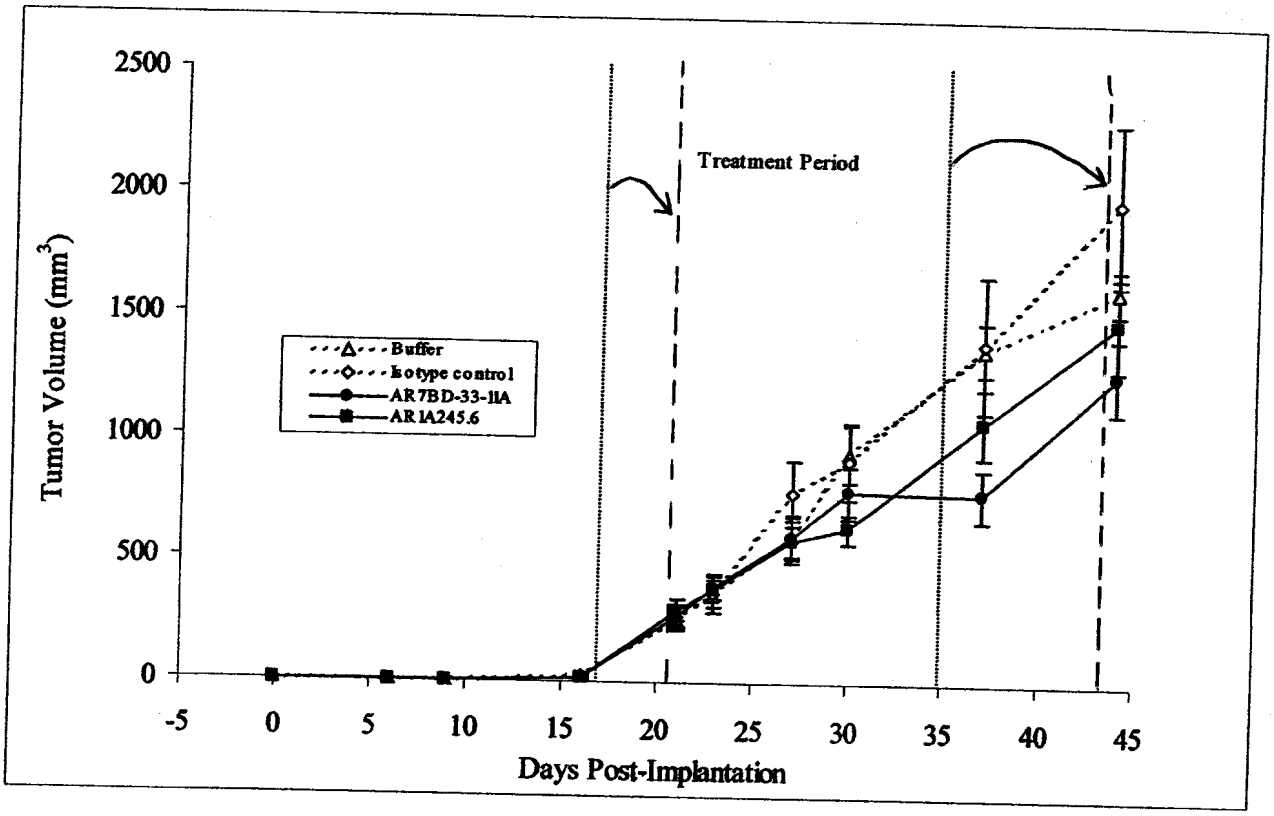
FIGURE 7


2500
2000
1500
1000
500
0
Tumor Volume (mm3)
-5
0
5
10
15
20
25
30
35
40
45
Days Post-Implantation
Treatment Period
Buffer
Isotype control
AR7BD-33-IIA
AR1A245.6